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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,706	10/20/2003	Joseph Loscalzo	102258.170 US2	2830

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EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,706	LOSCALZO ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-169* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-169* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants status inquiry filed 04/26/2005 is acknowledged and entered. An Office Action follows on said inquiry.

2. Claims 1 -169 are pending.

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Group I – Claims 1-25 drawn to a composition, classified under Class 424, Subclass 44.4.
- Group II - Claims 26-27, 38-42 and 44-90 drawn to a method of treating a vascular disease, classified under Class 424, Subclass 451.
- Group III – 28, 43 and 91-122 drawn to Raynaud's Syndrome Control, classified under
- Class 424, Subclass 94.1.
- Group IV – Claims 29-37 drawn to a oral drug, classified under Class 424, Subclass 78.02.
- Group V - Claims 123-144 drawn to a method of treating a vascular disease, classified under Class 424, Subclass 78.06.
- Group VI - Claims 145-163 drawn to a transdermal patch to treat vascular disease, classified under Class 424, Subclass 449.
- Group VII – Claim 164-169 drawn to a method to treat a vascular disease, classified under Class 424, Subclasses 484.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups I, III- IV and VI are related to each other as combination/ sub-combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the sub-combination as claimed for patentability, and (2) that the sub-

combination has utility by itself or in other combinations [MPEP § 806.05(c)]. In the instant case, the combination does not require the particulars of the sub-combination as claimed for patentability because the combination, due to the presence of additional ingredients, would be patentable even if the sub-combination was known and non-obvious, assuming that the prior art does not teach or suggest the presence of the additional ingredients recited in the combination claims. The sub-combination has utility of its own because of the presence of multiple ingredients (e.g. a ubiquinone as an antioxidant in a mixture with a catalase).

Inventions in Groups I, III-IV and VI are related to inventions in Group II, V and VII as product and use thereof. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product [MPEP § 806.05(h)]. The method of invention encompassed in Group II invention can be accomplished with a number of pharmaceutical products available in the market place as over the counter and prescription medications. Similarly, product of invention in Group I for e.g., has numerous materially different uses than those claimed. For e.g., to simply control any vascular disease.

Inventions in Groups II, V and VII are unrelated to each other because they are directed to different inventions that are not connected in design, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claims encompassed in Group III are directed to a method to treat a vascular disease via administering an HMG-CoA inhibitor, whereas the one in Group VIII requires an antioxidant enzyme and would therefore, may not be practiced together.

The inventions discussed above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (i.e., Class and subclass), and their recognized diverse subject matter, they would illicit an undue burden on the examiner to search and examine all the inventions in groups I- VI in one single application. Furthermore, the criteria for

patentability may not be same for each of the recited groups and what may be applicable for one group may not at all be applicable to other group. Thus, restriction for examination purposes as indicated is proper.

5. Applicants are advised that a reply to this requirement must include an identification of an invention elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

6. Upon the allowance of a generic claim, applicants will be entitled to consideration of additional claims which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141. Currently, Claims 1, 12, 15 and 19 are generic claim. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR §1.116; amendments submitted after allowance are governed by 37 CFR §1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C.§§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b). Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner

can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1655
(571) 272-0923

March 20, 2006

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651